Lewis Stein, Esq.
NUSBAUM, STEIN,GOLDSTEIN,
BRONSTEIN & KRON, P.A.
20 Commerce Boulevard, Suite E
Succasunna, NJ 07876
nsgbk.office@verizon.net
(973) 584-1400
Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
for the
DISTRICT OF NEW JERSEY

CHAYA GROSSBAUM and MENACHEM GROSSBAUM, her spouse, individually and as *guardians ad litem* of the infant ROSIE GROSSBAUM,	
Plaintiffs,	CIVIL ACTION NO. 07-CV-1359 (GEB)
vs.	
GENESIS GENETICS INSTITUTE, LLC, of the State of Michigan, MARK R. HUGHES, NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITALS CENTER, both corporations in the State of NEW YORK, ABC CORPS. 1-10, JOHN DOES 1-10,	
Defendants.	

CERTIFICATION OF LEWIS STEIN, ESQ.

1. I am an attorney at law in the State of New Jersey having been admitted to practice in the United States District Court for the District of New Jersey in 1961. I have been the

sole attorney who has been involved in the processing of this litigation on behalf of the Plaintiffs.

2. The extraordinary application being made to the District Court is predicated on the oral rulings made by U.S. Magistrate Judge Esther Salas on September 21, 2009 followed by her orders of September 23, 2009 (Doc. No. 29) and the Court's Letter Order of November 23, 2009 (Doc. No. 33). This motion would have been made in the first instance to the Magistrate Judge, but the Magistrate Judge declined to address our request for permission to file the formal motion which permission was required by the first scheduling order of December 12, 2007. (See request made in last paragraph on page 4 of Plaintiffs' letter of 10/13/09, Doc. No. 31).

3. While what has taken place in the months of September, October and November 2009, which are the precipitating events for this Motion, any fairness assessment of the recent orders (oral and written) must include the contextual history of discovery in this 2½ year old litigation with its original scheduling order dated December 12, 2007 and six succeeding scheduling orders thereafter. That context is discussed subsequently in Paragraphs 16, 17 and 18.

4. By letter dated August 25, 2009 (Doc. No. 22), the Plaintiffs advised the Magistrate Judge of the difficulties in meeting the Court's most recent scheduling order of June 10,

2009 (Doc. No. 20). That letter emphasized:

(a) That Plaintiff was denied a complete copy of her laboratory records at Genesis Genetics for almost 2½ years until delivery on May 8, 2009.

(b) Depositions of the five medical service providers at NYU in New York took place on five separate occasions between March 11, 2009 and July 13, 2009 notwithstanding Plaintiff's extensive efforts to obtain depositions on earlier dates and to double-up on the obviously short depositions of the nurses and the embryologists to save time and avoid delay.

(c) This delayed a full and complete analysis by our consultant expert, Dr. Garry R. Cutting, Professor of Pediatrics and Medicine, and Director of the DNA Diagnostic Laboratory, Institute of Medicine, at Johns Hopkins University. Our consultation with Dr. Cutting took place in Baltimore on July 7, 2009. At that meeting, the significance of the deposition of the embryologist Alexis Adler at NYU which was scheduled for July 13, 2009 was made known. That deposition did take place on that date notwithstanding our request to do it earlier on June 4, 2009. A transcript was sent to Dr. Cutting on August 4th. We then awaited his report anticipated prior to the discovery end date provided for in the scheduling order of June 10th. The failure of the report to arrive precipitated our letter to the Magistrate Judge of August 25, 2009 (Doc. No. 22).

Parenthetically, as we indicated to the Magistrate Judge on the record, the undersigned takes vacation during the month of August at a vacation home in Lennox, Massachusetts and returns midweek for two days only to attempt to keep the cases moving.

(d) Following the July 7th conference with Dr. Cutting, the need for further expertise from a specialist in laboratory techniques for pre-implantation genetic testing as opposed to a physician utilizing the PGD studies in treating patients through the *invitro* fertilization processes was understood. Such expertise was sought for a number of months early in the litigation (see confidential memo dated January 17, 2008 requested by the Magistrate Judge in the original scheduling order annexed hereto as Exhibit C) but became more significant following the deposition of defendant Hughes on February 21, 2009 and the consultation with Dr. Cutting on July 7, 2009.

(e) This letter of August 25, 2009 to the Magistrate Judge was Plaintiffs' fifth letter over the prior two years advising that the Defendant, Genesis Genetics, had not provided a full and complete record of the laboratory studies until May 8, 2009. (See letters dated January 17, 2008 (Exhibit C), February 21, 2008 (Exhibit D), January 22, 2009 (Exhibit E), May 6, 2009 (Exhibit F) and August 25, 2009 (Doc. No. 22).)

(f) Finally, Plaintiffs' letter of August 25, 2009 (Doc. No. 22) further indicated that the Plaintiffs contemplated

damage experts' reports, which had not been commissioned until the Plaintiffs were secure in the knowledge that a claim for malpractice had substance. This practice was consistent with the original discovery plan filed by the parties at the outset of litigation. The reasonableness for this discovery plan should be manifest since ultimately the Plaintiffs were required spend $7,861 with respect to obtaining damage reports: a report from the treating cystic fibrosis specialist of the Infant Raizel Grossbaum at the Respiratory Center for Children at Morristown Memorial Hospital ($1,000); the life care plan ($4,386); and the economist ($2,475).

5. Plaintiffs' letter of August 25th precipitated the first communication of any kind to the Magistrate Judge by New Jersey counsel for Genesis Genetics, LLC, to wit a letter dated August 27th (Doc. No. 23), asking the Magistrate Judge to refuse any extension of time to file experts' reports and seeking leave to file dispositive summary judgment motions. That letter referred to document discovery as being completed by May 8, 2009 and failed to acknowledge that the document provided on May 8, 2009 was the critical document upon which the underpinnings of the entire case against Genesis Genetics would be based. Moreover it accused Plaintiffs' counsel of willful disregard of the Court's case management and scheduling orders notwithstanding (a) the discovery plan that defendant agreed to

contemplating a bifurcated presentation of expert reports (liability and damages) and (b) the numerous letters and pleas to the Magistrate Judge that the defendants were not cooperating in providing discovery AND NOT A SINGLE LETTER OF COMPLAINT FROM DEFENDANTS PRIOR TO ITS LETTER OF AUGUST 27, 2009.

6. Plaintiff responded to the defendant Genesis Genetics' letter of August 27th with a detailed history of the discovery and difficulties created by the defendant Genesis Genetics with respect to compliance with discovery orders. The undersigned hereby certifies to the accuracy to the content of that letter of September 2, 2009 (Doc No. 24).

7. The undersigned, counsel for the Plaintiffs, acknowledges that he failed to note that the scheduling orders routinely lumped together the required production of both liability and damage experts on the same date. More will be said about this subject by way of argument in the Brief annexed.

8. In response to the aforementioned letters, the Magistrate Judge scheduled a status conference for September 21, 2009. Counsel for Defendant NYU requested that the conference be held telephonically, but the undersigned objected and the conference was held in Chambers. See our letter of September 14, 2009 (Doc. No. 27).

9. While there is no transcript of that in-chambers session, I am confident in stating that the atmosphere created

by the Magistrate Judge was hostile, especially to Plaintiffs. Plaintiff does not contend that this attitude was the result of partiality but created by burdens of case management. Plaintiff was told that the discovery plan which called for experts reports in two stages, liability first and damages later, meant nothing and was not contemplated by the Court's scheduling orders. There was to be no further fact discovery and a stringent schedule would be imposed on Plaintiffs to produce experts' reports. Counsel were then ordered into the Courtroom to continue the conference on the record. Counsel were also advised that Judge Brown was now the District Court Judge of Record and a report to Judge Brown was required of the Magistrate Judge to explain the delay in making the case ready for trial. (See Doc. No. 30 at Page 28.)

10. As previously noted, a transcript does exist of these proceedings, and does reflect the disrespect manifested toward counsel. Since the status conference was originally scheduled for 1:30 p.m., Plaintiffs' counsel allowed a deposition scheduled for 3:00 p.m. in Millburn (less than ½ hour away) of a medical doctor to remain on his schedule. However, since the status conference was moving into the Courtroom at 3:00 p.m., Plaintiffs' counsel requested from the Magistrate Judge in open Court permission to telephone the deposition site to advise as to his whereabouts and that he would be late. The request was

denied by the Magistrate Judge. (See Doc. No. 30 at Page 20).

11. The Magistrate Judge then imposed a rigorous schedule on the Plaintiffs requiring that *curriculum vitaes* of all proposed expert witnesses be served upon the Defendants within four days (by Friday, September 25th) under penalty of witness preclusion and experts' reports from all experts, both liability and damages, be delivered within 60 days (by November 20th).

12. Plaintiffs complied and advised the Magistrate Judge by letter dated October 13th (Doc. No. 31) that the *curriculum vitaes* of Plaintiffs' experts were submitted as required. Plaintiffs' experts listed were as follows:

(a) Dr. Garry Cutting, Professor of Pediatrics and Medicine and Director of the DNA Diagnostic Laboratory, Institute of Genetic Medicine at Johns Hopkins University;

(b) Dr. Charles Strom, Medical Director, Genetic Testing Center, Nichols Institute, Quest Diagnostics, San Juan Capistrano, CA;

(c) Linda Lajterman, RN, a certified life care planner of Life Care Associates;

(d) Dr. Arthur Atlas, Director, Respiratory Center for Children at Morristown Memorial Hospital, Morristown, NJ; and

(e) Dr. Matityahu Marcus, professor emeritus in economics at Rutgers University.

This Court may note that Plaintiffs anticipated an expert report from Svetlana Rechitsky, Ph.D., from Reproductive Genetics Institute, Chicago, IL as indicated in our letter of August 25th.

This came about because Plaintiff again called upon Dr. Horowitz who we were advised had left Reproductive Genetics Institute, Chicago, for the University of Illinois Medical Center, Chicago, IL. However, this did not materialize since after a delay of several weeks Plaintiffs were advised that Dr. Rechitsky's superiors would not allow her to participate in the litigation since Dr. Rechitsky's group competed with Defendant Dr. Mark Hughes' Genesis Genetics group in Detroit, and that they were also members of the same specialty societies in PGD testing— the same problem previously encountered with Dr. Horowitz in the first instance.

13. Plaintiffs were then advised in the contacts referred to in the previous paragraph that Dr. Charles Strom, Chief of Genetic Testing for Quest Diagnostics, a national laboratory company who was located in California would have suitable experience (i.e. on a similar level to Dr. Hughes) in the laboratory studies for PGD testing such as that was done at Genesis Genetics and could be approached to consult with Plaintiffs. This resulted in Dr. Strom becoming a witness in the case. His report, in addition to that of Dr. Cutting, which was finally received by the Plaintiffs on October 2, 2009 and immediately forwarded to the Defendants, as well as the reports of the damage experts were provided to the defendants by letter dated November 16, 2009 in full compliance with the scheduling

order of September 23, 2009.

14. The complexity of the medicine that underlies Plaintiffs' cause of action cannot be understated. Preimplantation genetic diagnosis (PGD) refers specifically to when one or both genetic parents have a known genetic abnormality and testing is performed on an embryo to see if it also carries that genetic abnormality. Embryos generated during an *in vitro* fertilization cycle are biopsied by removal of one or two cells which are then analyzed in a laboratory for the presence of the specific genetic abnormality. Non-affected embryos of suitable quality are then transferred into the uterus for subsequent implantation/pregnancy.

15. Two of the incontrovertible facts associated with the medical legal aspects of the case are: first, there is a limited number of consultants available to a patient (a plaintiff) to assist in evaluating and pursuing their case involving PGD testing; second, the nature and extent of fact discovery is in large measure the result of advice from experts and cannot always be compartmentalized and sequenced in a timeline that precedes the consultation with experts. Also the need for further fact discovery may come about by the positions of the defense and their experts.

16. In considering the context of the events that precipitated the Orders now before this Court, a curious point

of departure may be the letter by counsel for Genesis Genetics to the Court dated September 3, 2009 at Paragraph 3 where it states: "We see no reason to burden the court with a line-by-line response to the litany of long-since-resolved complaints in Plaintiffs' September 2, 2009 letter…". Plaintiffs' long list of complaints started with the letter to the Magistrate Judge on February 21, 2008 (apparently not e-filed but mailed to the Court. See copy attached as Exhibit D in which we advised that we had not, notwithstanding our requests that started in January 2007, been provided with a full and complete and useful copy of the Genesis Genetics' records. Although it was anticipated that Plaintiffs' request for complete records could be satisfied within 15 days of the date of the letter, the records were not provided. By letter dated March 14, 2008 we were advised by Stephen M. Leuchtman, Esq., Michigan counsel to Genesis Genetics and Mark Hughes as follows: "My client advises that the materials he has provided to you are all of those which or ever were at anytime in his possession or in the possession of Genesis Genetics".

17. Thereafter on January 22, 2009, Plaintiffs were required to advise the Magistrate Judge that not withstanding the scheduling order of October 14, 2008 (Doc. No. 18), requiring that Answers to Interrogatories be supplied by October 20, 2008, Defendants Genesis Genetics and Mark Hughes did not

provide answers until November 18, 2008, 28 days beyond the date of the order. That Scheduling Order also required depositions of the parties to be completed by December 19, 2008. Plaintiffs submitted to depositions at the first request of Defendants on December 17, 2008, but Dr. Hughes did not make himself available until January 19, 2009, which was then adjourned because counsel for Defendant NYU was not available and was not rescheduled until February 19, 2009. At Dr. Hughes' deposition it was admitted that Plaintiff had not been provided the entire medical chart. It was not until March 16, 2009, some 25 days later, that what purported to be the complete chart was provided to the Plaintiffs. But this submission was also incomplete since a significant portion of the chart were graphs described as "assay optimizations" that could only be properly understood if provided in color. A request for this record was forwarded to Genesis Genetics on April 6, 2009 and more than another month passed until the records as requested were provided to the Plaintiffs. Thus the assertion in our letter to the Magistrate Judge on September 2, 2009 that in fact it was not until May 8, 2009 that Plaintiffs could be informed of the quality of care afforded the Plaintiffs by Defendants, Genesis Genetics and Dr. Mark Hughes.

18. Defendant NYU was also less than attentive to the scheduling orders of the Magistrate Judge. Defendant NYU

provided Answers to Interrogatories on November 13, 2008 more than 25 days after the scheduling Order required. The deposition of Dr. Licciardi was not accommodated until March 11, 2009 and the depositions of the remaining providers at NYU were not completed until July 13, 2009.

19. The undersigned can comfortably represent to the Court that the information sought from the laboratory personnel at Genesis Genetics and document inspection as indicated in this motion could not have been understood without the benefit of consultation and the report of Dr. Charles Strom of the Nichols Institute of Quest Diagnostic Corporation located in San Juan Capistrano, California. This follows an in-person conference in California on November 9, 2009 and a report provided to the Defendants on November 16, 2009 in accordance with the scheduling order of September 23, 2009. The complexity of the subject matter should be apparent from the report, a copy of which is annexed hereto as Exhibit G.

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Date: December 4, 2009

/s/ Lewis Stein
Signature of Attorney

Lewis Stein, Esq.
Printed name

20 Commerce Blvd., Suite E
Succasunna, NJ 07876
Address

nsgbk.office@verizon.net
E-mail address

(973) 584-1400
Telephone number

EXHIBIT A

ORIGINAL

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CASE NO. 07-CV-1359 (HAA)

CHAYA GROSSBAUM and MENACHEM GROSSBAUM, her spouse, individually and as guardians ad litem of the infant ROSIE GROSSBAUM,

Plaintiffs,

vs.

GENESIS GENETICS INSTITUTE, LLC, of the State of Michigan, MARK R. HUGHES, NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITAL CENTER, both corporations in the State of New York, ABC CORPS, 1-10, and JOHN DOES 1-10

Defendants.

- x

DEPOSITION UPON ORAL EXAMINATION OF:
MARK R. HUGHES, M.D.

TRANSCRIPT of the deposition of the witness, called for Oral Examination in the above-captioned matter, said deposition being taken pursuant to Notice, taken by and before KATHLEEN HAGEN, a Notary Public and Certified Shorthand Reporter of the State of New Jersey, at the law offices of NUSBAUM, STEIN, GOLDSTEIN, BRONSTEIN & KRON, P.A., 20 Commerce Boulevard, Succasunna, New Jersey, on Thursday, February 19, 2009, commencing at 10:30 a.m.

PHILIP A. FISHMAN
COURT REPORTING AGENCY
89 Headquarters Plaza
4 Speedwell Avenue, Suite 440
Morristown, New Jersey 07960
(973) 285-5331
Fax (732) 605-9391

your attention as being born with cystic fibrosis, that you did PGD testing on?

A Four, I believe.

Q And these four are the four you mentioned?

A Yes.

Q And how many babies would you say you tested for cystic fibrosis mutations, in doing PGD testing, in total, over the time that you've been doing this work?

A I do not know, but over 1000.

Q Is there a particular ethnic group of people who have a higher incidence of cystic fibrosis mutations than others?

A Caucasions.

Q Now, it's reported that the testing for the screening testing for the CSF gene is 97 percent effective within Ashkanazi Jews, is that correct?

A Well, it's variable, depending on who's doing the testing and how many different mutations they're testing for, unless you actually sequence the gene entirely, you can't have a perfect test, and even then, you don't have a perfect test, but you reduce that percentage closer and closer to zero risk of having a mutation, the more mutations you test for. So some laboratories test for 20, some test for 40, some test

A Well, if we've had four errors in 1000 cases, it's significantly less than 1 percent.

Q And you figure you tell the people that?

A Yeah, we'll tell them -- the field of PGD quotes a risk of 3 to 5 percent error for this kind of testing, and for chromosome testing, it's even higher, and now as we are learning about the amazing discrepancies of cells inside of an embryo, we're learning that there's all sorts of reasons why a cell that you biopsy might not represent the whole embryo, so the field across the world quotes risks in 3, 4, 5 percent. In our personal program, it's less than 2, actually less than 1.

Q Okay. Do you have a reason as to why your program experiences, as you indicated, even less than 1 percent in the field and the field is quoting 3 to 5?

A Well, we do more of this than any other laboratory in the world, we've been doing it longer than any other laboratory in the world, so I think experience has something to do with it, but we know that in each family, so none of these tests are off the shelf, every one of them are custom designed for the unique DNA of each couple, because your DNA is unique on the planet, and the DNA that you and your partner mix together to make a baby is unique, and every time

EXHIBIT B

Genesis Genetics - Patient Application - Family Activity Log

[Home | Patient Information | Search Family | Search Disease | Search Hcp/Team | Maintenance | Oligo | Webmaster | FAQ | Logout]

Display Archived Records:

Add Family | Edit | Delete

Morganstern-Grossbaum.M/C.CF10+11.Grifo-NYU.2004#316

Family: Morganstern-Grossbaum.M/C

Family Name: Morganstern-Grossbaum.M/C

Family ID: 110000814

Initiated: 2004-03-08

Status: 12-Case Complete

Biopsy Target Date: 2004-07-17

View Barcodes

Subject Information | Health Care Providers | Activity Log | Notes & Attachments | Subject Submission | Biopsy Submission

Add Activity Cycle to Family | Delete

Activity Cycle: 1

Add Activity to Current Cycle | Edit | Delete

	Seq.	Category	Activity	Target-Date	Comp-Date	Assigned To
✓	1	Inquiry	Inquiry	2004-03-08	2004-03-09	Shannon Wiltse
✓	2	Pre-case Logistics	Diagnostic Report(s) Reviewed	2004-03-09	2004-03-09	Shannon Wiltse
✓	3	Pre-case Logistics	Conference Call	2004-03-25	2004-03-25	Mark Hughes
✓	4	Pre-case Logistics	Case Accepted	2004-03-25	2004-03-25	Mark Hughes
✓	5	Pre-case Logistics	Consent Form(s) Received	2004-05-25	2004-07-18	Matt Studt
✓	6	Clinical Samples En-Route	Clinical Samples Received	2004-03-31	2004-03-31	Susan Brown
✓	7	Diagnostic Strategy	Design Diagnostic Strategy	2004-04-16	2004-04-13	Matt Studt
✓	8	Diagnostic Strategy	Diagnostic Optimization	2004-05-14	2005-05-10	Susan Brown
✓	9	Coordinate for Biopsy	Coordinate Micro-manipulation	2004-05-14	2004-04-14	Shannon Wiltse
✓	10	Coordinate for Biopsy	Reagent Kit Delivered	2004-03-22	2004-03-22	Susan Brown
✓	11	Treatment Cycle in Progress	Approval to Begin Treatment C..	2005-05-10	2005-05-12	Mark Hughes
✓	12	Retrieval Scheduled	Retrieval Date	2004-07-15	2004-07-15	Shannon Wiltse
✓	13	Biopsy Scheduled	Biopsy Date	2004-07-17	2004-07-17	Shannon Wiltse
✓	14	Diagnostics In Progress	Genetic Diagnostics	2004-07-18	2004-07-19	Susan Brown
✓	15	Results Forwarded to Clinic	Report(s) Generated / Clinic ..	2004-07-19	2004-07-19	Mark Hughes
✓	16	Post-case Follow-up	Awaiting Pregnancy Results	2005-01-25	2005-03-28	Shannon Wiltse
	17	Post-case Follow-up	Prenatal Testing	2005-10-25		
✓	18	Post-case Follow-up	Delivery Due Date	2005-04-07	2005-08-05	Shannon Wiltse
	19	Post-case Follow-up	Non-transferred Material Rece..			
✓	20	Cycle Complete	Cycle Complete	2005-08-05	2005-08-05	Shannon Wiltse

[Frequently Asked Questions]

EXHIBIT C

NUSBAUM, STEIN, GOLDSTEIN, BRONSTEIN & KRON

A Professional Corporation
Counsellors At Law

LEWIS STEIN*
ALAN D. GOLDSTEIN
RONALD W. BRONSTEIN
PATRICIA E. ROCHE◦
LARRY I. KRON
ROBERT D. KOBIN¤
SHARON L. FREEMAN+ ^
SUSAN B. REED
STEVEN J. LOEWENTHAL ◊

20 Commerce Boulevard, Suite E
Succasunna, New Jersey 07876
973-584-1400
Fax: 973-584-8747
Email: nsgbk.office@verizon.net

- Of Counsel -
PAUL R. NUSBAUM

CERTIFIED BY THE SUPREME COURT OF NEW JERSEY AS A
*Civil Trial Attorney
◦Matrimonial Attorney
^Workers' Compensation Attorney
¤Member Florida Bar
◊Member New York Bar
+Member Pennsylvania Bar

January 17, 2008
Via Facsimile (973) 645-2469

Hon. Esther Salas
U.S. Magistrate Judge
United States District Court
District of New Jersey Newark
Martin Luther King Jr., Fed. Bldg. & Cthse.
50 Walnut St.,
Newark, NJ 07102

Re: Grossbaum v. Genesis Genetics Institute, LLC, et al.
Case # 07-CV-1359 (HAA)
Confidential Memorandum

Dear Judge Salas:

In accordance with your directive at the initial Case Management Conference, we hereby submit this Confidential Memorandum as to the status of Plaintiffs' evaluation of a potential case against the genetic testing laboratory, Genesis Genetics, and NYU Medical Center, the situs of the preimplantation, embryonic extraction and subsequent post-testing implantation, that resulted in the birth of a cystic fibrosis baby to the Plaintiffs.

As we indicated at the Conference, investigation of this matter commenced in January 2007 with a request to Genesis Genetics Institute, Detroit, Michigan, for copies of the genetic testing done on embryos forwarded to it by NYU Medical Center. Repeated requests for the records received no attention from Genesis Genetics until commencement of the suit in April 2007 and further prodding of defense counsel, when the records were finally received on August 27, 2007.

When first consultation was made in January 2007, our investigation included a consultation in Parsippany, New Jersey with one of the few genetic testing laboratories in the country, where we were educated in the nature of the processes (to the extent possible in an one hour conference) and subsequent readings.

No further efforts at evaluation could be undertaken until the records were received. There followed a series of contacts initially with Dr. Barbara Burton, a fertility expert at Northwestern University Medical School in Chicago, who referred us to Allen Horwitz, M.D., Ph.D., since preimplantation genetic diagnosis for gene disorders is very much a subspecialty of fertility practice. Dr. Horwitz is connected to the Reproductive Genetics Institute in Chicago. On September 28, 2007, we forwarded the records to Dr. Horwitz. After approximately four weeks we received a responsive phone call in which Dr. Horwitz indicated certain areas of interest concerning the quality of testing done at Genesis Genetics. However, being in Chicago and the Defendants, Genesis Genetics and Mark Hughes, being in Detroit, and competitors in business, suggested that more objectivity in the evaluation may better be had by contacting Dr. Garry R. Cutting at Johns Hopkins University School of Medicine. Dr. Cutting is the Director of the Institute of Genetic Medicine at Johns Hopkins. Therefore, on December 7, 2007, following a number of phone calls, we were able to establish contact with Dr. Cutting who indicated a willingness to evaluate the file. Dr. Cutting is Professor at the Department of Pediatrics, Director of the DNA Diagnostic Laboratory and Director of the Medical Genetics Training Program at Johns Hopkins. Following our telephone conversation on December 7th, we forwarded to Dr. Cutting the complete records for his opinion and advice as to whether he would be an expert in this case on behalf of the Plaintiffs.

Not having received a reply from Dr. Cutting, in the New Year we telephoned and were advised by his assistant that Dr. Cutting still had the matter under advisement and, due to the holiday season, had not given it his attention and that we would be hearing from him shortly. To date, we have not had a report from Dr. Cutting and await his response.

In addition, contemporaneous with our attempts to involve Dr. Cutting (needless to say, very much an academic and not a forensic physician), we made contact with Dr. William Kearns. Dr. Kearns discussed the matter with me on January 16th and has agreed to consider being an expert witness in this matter. He reports prior experience with the Defendants, Genesis Genetics and Dr. Mark Hughes, in which questions have been raised of the quality of performance by the Defendant, therefore giving reason to believe that there is a real potential for a claim.

In summary, we are at this point awaiting a report from Dr. Cutting, abiding affirmation of the merits of the Plaintiffs' claim and, as a backup, Dr. Kearns who may be more accessible to the litigation requirements.

I trust that this Memorandum fully apprises the Court of the status of Plaintiffs' efforts to assemble the necessary evidence to move forward. Under these circumstances, we plan to go forward. Of course, further revelations which may make success questionable will result in our advice to the Court of a termination of our interest in the case.

I trust this is in compliance with the Court's request for a Confidential Memorandum.

Respectfully yours,

Lewis Stein

LS:svd
Total pages faxed=3

EXHIBIT D

NUSBAUM, STEIN, GOLDSTEIN, BRONSTEIN & KRON

A Professional Corporation
Counsellors At Law

LEWIS STEIN*
ALAN D. GOLDSTEIN
RONALD W. BRONSTEIN
PATRICIA E. ROCHE◦
LARRY I. KRON
ROBERT D. KOBIN¤
SHARON L. FREEMAN+ ^
SUSAN B. REED
STEVEN J. LOEWENTHAL ◊

20 Commerce Boulevard, Suite E
Succasunna, New Jersey 07876
973-584-1400
Fax: 973-584-8747
Email: nsgbk.office@verizon.net

- Of Counsel -
PAUL R. NUSBAUM

CERTIFIED BY THE SUPREME COURT OF NEW JERSEY AS A
*Civil Trial Attorney
◦Matrimonial Attorney
^Workers' Compensation Attorney
¤Member Florida Bar
◊Member New York Bar
+Member Pennsylvania Bar

February 21, 2008

U.S. Magistrate Judge Esther Salas
United States District Court
50 Walnut Street
PO Box 999
Newark, NJ 07101

RE: Grossbaum v. Genesis Genetics, et al.
Civil Case No.: 07-CV-1359 (HAA)

Dear Judge Salas:

On December 17, 2007 you entered a Pretrial Scheduling Order with respect to this matter based on plaintiffs' expectation that a report would be forthcoming from our consultant in time to enable us to determine the viability of the plaintiffs' claims in this litigation. As per our confidential letter of January 17, 2008 we advised the Court of the status of our investigation.

We finally received this day an oral report from Garry R. Cutting, M.D. of the John Hopkins University of Medicine Institute of Genetic Medicine indicating that the records that were provided by Genesis Genetics did not contain certain studies which, if they existed, would be necessary for his opinions and would enable him to respond to the pertinent legal questions in this case.

To provide him with a response to his request for further records, we have this day forwarded said request to counsel for defendant Genesis Genetics. See letter enclosed herewith.

On the basis of his advice, and the obvious indication that plaintiff is consulting with the highest level of academic professionals that could be imagined, we ask that a revised Pretrial Scheduling Order be entered to allow all of the dates set forth therein to

be advanced 45 days. This anticipates a 15 day response from counsel for Genesis Genetics and a 30 day opportunity for Dr. Cutting to advise plaintiff of his final impressions.

Respectfully yours,

Lewis Stein

LS:lh
Cc: R. Scott Eichhorn, Esq.
Stephen N. Leuchtman, Esq.
Thomas E. Redburn Jr., Esq. and Sarah Blaine, Esq.

NUSBAUM, STEIN, GOLDSTEIN, BRONSTEIN & KRON

A Professional Corporation
Counsellors At Law

LEWIS STEIN*
ALAN D. GOLDSTEIN
RONALD W. BRONSTEIN
PATRICIA E. ROCHE◦
LARRY I. KRON
ROBERT D. KOBIN¤
SHARON L. FREEMAN+ ^
SUSAN B. REED
STEVEN J. LOEWENTHAL ◊

20 Commerce Boulevard, Suite E
Succasunna, New Jersey 07876
973-584-1400
Fax: 973-584-8747
Email: nsgbk.office@verizon.net

- Of Counsel -
PAUL R. NUSBAUM

CERTIFIED BY THE SUPREME COURT OF NEW JERSEY AS A
*Civil Trial Attorney
◦Matrimonial Attorney
^Workers' Compensation Attorney
¤Member Florida Bar
◊Member New York Bar
+Member Pennsylvania Bar

February 21, 2008

Stephen N. Leuchtman, Esq.
Ravid and Associates, PC
23855 Northwestern Highway
Southfield, MI 48075

Thomas E. Redburn Jr., Esq.
Sarah Blaine, Esq.
LOWENSTEIN SANDLER PC
65 Livingston Avenue
Roseland, NJ 07068

RE: Chaya Morganstern-Grossbaum and Menachem Grossbaum vs. Genesis Genetics and NYU

Dear Mr. Leuchtman, Mr. Redburn and Ms. Blaine:

We were finally able to consult with one of our experts, Dr. Garry R. Cutting of the John Hopkins University School of Medicine Institute of Genetic Medicine who has had an opportunity to review the medical chart provided by you.

Our consultation with Dr. Cutting included an inquiry of the following questions:

Using Dr. Hughes' technology, were appropriate studies undertaken?
Were the results reported appropriate based on the information contained in the records?
In addition, from our limited understanding of the records, as to the implantation, it appears that one of the two embryos that were deemed appropriate for implantation was not used since it was degraded and not believed capable of successful implantation. It is my understanding that Nos. 8 & 10 were approved by Genesis Genetics but that No. 10 became degraded and No. 7 was

substituted. Apparently the testing done by Genesis Genetics did not include the husband's mutation. Could it be said that this substitution would substantially increase the risk of a cystic fibrosis child above what would have been expected under any appropriately done evaluations?

Dr. Cutting finally gave us an oral report today in which he advised us that his answers to questions mentioned above are related to a further inquiry as to whether additional records exist at Genesis Genetics relating to the genetic studies of the mutation relating to the father Menachem Grossbaum.

To that end, we are enclosing a copy of the medical records provided by you as requested from Genesis Genetics. Kindly confirm at your earliest possible time the existence of further records relative to studies made of the zygote obtained from the husband.

In the event that there are no such records, we would expect a response from you that would enable us to tell Dr. Cutting that no further studies were made in connection with this case.

Your prompt, attention to this matter would be appreciated. In addition, please be advised that we are providing Magistrate Judge Salas with a copy of this letter to support a request that we receive an extension of the pretrial scheduling order to undertake discovery pending response from Dr. Cutting.

Very truly yours,

Lewis Stein

LS/em
Encs.

cc: U.S. Magistrate Judge Esther Salas
R. Scott Eichhorn, Esq.

EXHIBIT E

NUSBAUM, STEIN, GOLDSTEIN, BRONSTEIN & KRON

A Professional Corporation
Counsellors At Law

LEWIS STEIN*
ALAN D. GOLDSTEIN
RONALD W. BRONSTEIN
PATRICIA E. ROCHE◦
LARRY I. KRON
ROBERT D. KOBIN¤
SHARON L. FREEMAN+ ^
SUSAN B. REED
STEVEN J. LOEWENTHAL ◊

20 Commerce Boulevard, Suite E
Succasunna, New Jersey 07876
973-584-1400
Fax: 973-584-8747
Email: nsgbk.office@verizon.net

- Of Counsel -
PAUL R. NUSBAUM

CERTIFIED BY THE SUPREME COURT OF NEW JERSEY AS A
*Civil Trial Attorney
◦Matrimonial Attorney
^Workers' Compensation Attorney
¤Member Florida Bar
◊Member New York Bar
+Member Pennsylvania Bar

January 22, 2009

Hon. Esther Salas, U.S.M.J.
US District Court
District of New Jersey
50 Walnut Street
Newark, NJ 07102

RE: Grossbaum vs. Genesis Genetics, et al.
Civil Action No.: 07-CV-1359 (HAA)

Dear Judge Salas:

I am compelled to write to you regarding your most recent Scheduling Order of October 14, 2008.

In writing this letter it is not my intention to complain about actions taken by counsel, but merely to report to the court the facts and circumstances of discovery in the matter as they now appear.

Interrogatory answers were received from defendant Genesis Genetics on November 18, 2008 which completed the exchange of interrogatories between the parties.

Depositions of the plaintiff were then scheduled for December 17th at which time the deposition of plaintiff Chaya Grossbaum was in the large measure completed, albeit unfinished as to damages. The deposition of Menachem Grossbaum, who was in attendance on December 17th, was to be rescheduled for another day.

The depositions of defendants' representatives, Dr. Mark Hughes of Genesis Genetics in Detroit, Michigan and Dr. Frederick Licciardi for NYU, remain outstanding.

Dr. Mark Hughes' deposition had been scheduled for January 16, 2009 at 10:00 a.m. in New York City, and was adjourned by defense counsel because of a conflict with a scheduled trial date. This deposition is now scheduled for February 19, 2009 in New Jersey. A firm date has not yet been scheduled for Dr. Licciardi.

Obviously, as so often happens in the real life of litigation lawyers, the compliance with the court's scheduling orders on occasion collide with the extent of cooperation of institutional defendants and the fulfillment of their discovery obligations.

My concern is that compliance with this Court's Scheduling Order should not adversely impact the plaintiffs' claim.

Respectfully yours,

Lewis Stein

LS/em
cc: R. Scott Eichhorn, Esq.
John F. Basiak, Esq.
Stephen N. Leuchtman, Esq.

EXHIBIT F

NUSBAUM, STEIN, GOLDSTEIN, BRONSTEIN & KRON

A Professional Corporation
Counsellors At Law

LEWIS STEIN*
ALAN D. GOLDSTEIN
RONALD W. BRONSTEIN
PATRICIA E. ROCHE◦
LARRY I. KRON
ROBERT D. KOBIN¤
SHARON L. FREEMAN+ ^
SUSAN B. REED
STEVEN J. LOEWENTHAL ◊

20 Commerce Boulevard, Suite E
Succasunna, New Jersey 07876
973-584-1400
Fax: 973-584-8747
Email: nsgbk.office@verizon.net

- Of Counsel -
PAUL R. NUSBAUM

CERTIFIED BY THE SUPREME COURT OF NEW JERSEY AS A
*Civil Trial Attorney
◦Matrimonial Attorney
^Workers' Compensation Attorney
¤Member Florida Bar
◊Member New York Bar
+Member Pennsylvania Bar

May 6, 2009

Hon. Esther Salas, U.S.M.J.
US District Court
District of New Jersey
50 Walnut Street
Newark, NJ 07102

RE: Grossbaum vs. Genesis Genetics, et al.
Civil Action No.: 07-CV-1359 (HAA)

Dear Judge Salas:

I regret to advise the Court that our efforts to move forward with discovery in accordance with the Court's Scheduling Orders have been frustrated for many months by the unwillingness of Defendant, Genesis Genetics, to comply with our requests for the records created by that company. As may be seen from the enclosed correspondence dated March 5, 2009 to Genesis Genetics' defense counsel, we have been trying for more than two years to obtain a full and complete copy of the records of Genesis Genetics.

As the letter stated, it was not until Defendant, Mark Hughes', deposition on February 19, 2009, that we became aware that the records provided previously had been incomplete. One month passed before we were able to obtain a copy of the additional records, which were received on March 16th. Even though Dr. Hughes and the Defendant, Genesis Genetics, must have realized that the photocopy of the records we received would not provide our expert with a complete understanding of the records since the actual records were color coded and the color coding would be required for evaluation purposes, no color copy was provided. Thereafter, following advice by our expert that the records of Genesis Genetics that we had received on March 16th had to be color coded, I wrote to defense counsel, Stephen Leuchtman, Esq., requesting the color copy by letter dated April 6th, a copy which is annexed hereto. No response was forthcoming and, again on April 24th, I faxed a reminder letter to Mr. Leuchtman, a copy which is also annexed hereto.

To date, we do not have a full and complete useful copy of Defendant, Genesis Genetics', records. For this reason, we have been unable to obtain the final opinions of Plaintiffs' expert.

For all of the Court's involvement, we are still at the starting gate of this litigation, although it now is more than 20 months since Defendant, Genesis Genetics, had filed its Answer.

We must call upon the Court to invoke its authority with respect to the cooperation and compliance of Defendant, Genesis Genetics, with Plaintiffs' reasonable requests for documents in this matter.

Respectfully submitted,

Lewis Stein

LS:svd
cc: Stephen N. Leuchtman, Esq.
John F. Basiak, Esq.
R. Scott Eichhorn, Esq.

EXHIBIT G

Quest Diagnostics Incorporated

33608 Ortega Highway
San Juan Capistrano, CA 92675-2042
949.728.4000
www.QuestDiagnostics.com

Quest
Diagnostics

November 12, 2009

Lewis Stein
Nusbaum, Stein, Goldstein, Bronstein & Kron
20 Commerce Boulevard, Suite E
Succasunna, New Jersey 07876-1348

In re: Chaya Morganstern and Menachem Grossbaum

Dear Mr. Stein,

I have sent you my curriculum vita under separate cover. As you know I was the Medical Director and the Director of DNA Laboratory at Reproductive Genetics Institute in Chicago from May, 1988 to October, 2000. As such I was a pioneer in the field of preimplantation genetic diagnosis (PGD) and am the first author on the first publication describing preimplantation diagnosis for Cystic Fibrosis appearing in the journal *Lancet* in 1990. As such I consider myself to be an expert in the field of PGD.

I have reviewed the materials you sent me regarding this case and have reached some conclusions regarding the appropriateness of care in this case. Before I go into the conduct of this case, I would like to point out a clear factual inaccuracy that I have discovered that may have bearing on the integrity of defendants in this action.

In the deposition from Mark Hughes dated February 19, 2009, on page 18, lines 23 and 24, he states in response to a question regarding PGD, "…it's been going on since I invented the technology, 19 years ago." Mark Hughes did not invent PGD. The initial publication describing PGD was from Alan Handyside et al that appeared in the journal *Nature* in 1990. The first description of PGD for Cystic Fibrosis or for any other single gene disorder was published by my group that same year (see above). In no way can Mark Hughes justify the claim that he invented this technology. In fact Mark Hughes attended a workshop that we hosted where we taught PGD techniques to those wanted to learn them.

Quest Diagnostics Incorporated

33608 Ortega Highway
San Juan Capistrano, CA 92675-2042
949.728.4000
www.QuestDiagnostics.com

Quest
Diagnostics

Now to the specifics of the case. Chaya Morganstern-Grossbaum and Menachem Grossbaum presented for PGD to the NYU fertility center. Routine CF carrier detection had determined that Chaya Grossbaum was a carrier of the mutation G542X and Menachem was a carrier for delta F508. Thus this couple was at a 25% risk of having a child affected with CF. The situation in which each parent carries a different CF mutation is technically referred to compound heterozygosity. At the time this couple presented they should have been informed that this particular situation is extremely risky when performing PGD on blastomere biopsies because of a well known phenomenon known as allele drop out (ADO). In every cell there are 2 copies of the CF gene. When analyzing a single cell, it is well known that sometimes one of the 2 genes is not amplified by the PCR reaction and therefore it not analyzed in the diagnostic procedure. ADO has a much higher rate in blastomeres than polar bodies that are the other material being used for PGD at this time. So when each parent carries a different mutation, the blastomere will ALWAYS contain at least one copy of the normal gene. So there is no way to be sure whether a blastomere whose analysis shows only the normal gene actually is a blastomere with 2 normal copies of the CF gene or actually has one normal copy and one mutant gene that has suffered from ADO and therefore hasn't been identified. Since ADO rates in blastomeres has been shown by many authors to be at least 20% (and some authors have shown as high as 70%), the PGD on blastomeres in couples with compound heterozygosity has an unacceptably high error rate.

Thornhill and Snow write in a review of PGD "…for compound heterozygous or autosomal dominant conditions, the consequences of ADO can be catastrophic, as misdiagnosis and subsequent transfer of affected embryos can occur."

Because of this inherent difficulty with PGD performed on blastomeres in compound heterozygous couples, two methods were developed to improve diagnostic accuracy. The first is the use of linked markers to detect ADO when it occurs in order to prevent misdiagnosis. We have shown that the use of 1 linked marker reduces the undetected ADO rate approximately 50% and the use of 3 linked markers virtually eliminates misdiagnosis due to undetected ADO. For this couple, in order to develop an assay incorporating linked markers, other family members would have had to be studied in order to determine the haplotypes of the CF mutations. This would have involved collecting samples from siblings and / or parents of Chaya and Manachem. There is no evidence that this was suggested or offered as a possibility.

A second method to reduce diagnostic errors in this situation is to perform the PGD on polar bodies rather than on blastomeres. The ADO rate in polar bodies is approximately 5 fold less than in is blastomeres. In addition, due to a phenomenon called crossing over, approximately 50% of first polar bodies are heterozygous, eliminating the possibility of a misdiagnosis due to ADO altogether. Linked markers could have been incorporated into the polar body diagnosis also thereby further reducing the possibility for diagnostic errors. Both these alternatives were available at the time from Reproductive Genetics Institute in Chicago.

Quest Diagnostics Incorporated

33608 Ortega Highway
San Juan Capistrano, CA 92675-2042
949.728.4000
www.QuestDiagnostics.com

Quest
Diagnostics

There is no evidence that this couple was offered either of these alternative procedures which would have greatly reduced the opportunity for diagnostic error. Simply telling the couple "this is a research procedure" or this is "imperfect" ignores the fact that there were two alternative procedures available at the time that afforded a much higher likelihood of diagnostic accuracy that were not presented to the family.

In the unlikely event that a compound heterozygous couple was presented with the alternatives and still insisted on going forward with PGD by blastomere biopsy without using linked markers the couple should have been informed that the potential for misdiagnosis varies with the apparent genotype of the embryo.

The lowest risk of a misdiagnosis would be in an embryo that appeared to inherit only the normal alleles from both parents. In this situation an affected child could be born only if ADO occurred during the analysis of both mutations. Since the likelihood of ADO occurring in a single mutation analysis in a blastomere is approximately 25% the probability of having ADO occur simultaneously for two mutations in the same blastomere analysis is 25% (0.25) multiplied by 25% (0.25) or 6.2%. Thus the chances of an embryo being affected when both mutation analyses are successful and both showing normal genes only would be 6.2%. Unfortunately no single embryo in this case showed that result.

The embryos transferred in this case were numbers 7 and 8.

Embryo 7 had no result for the father's mutation and an apparent normal allele for the mother's mutation. The failure to obtain analysis for the paternal mutation indicates that the DNA from this blastomere was at least partially degraded making the likelihood of ADO in the analysis of the maternal allele even higher than the 25% I quote to my patients. Since there are no results for the paternal allele, I would estimate the chances of this embryo being affected with CF to be at least 15% - 20% and probably higher.

The analysis for Embryo 8 demonstrated that the blastomere contained the mutant maternal CF allele and the analysis of the paternal allele revealed apparently normal results. However, given an ADO rate of 25%, the chances of this embryo being affected are approximately 25%.

Thus the 2 embryos transferred both had risks of being affected which is similar to the priori risk of 25% for any couple who are carriers for a recessive genetic disease without any PGD performed. Thus the chances of this couple having an affected child following the expensive procedure are similar to their chances of having an affected child if nothing was done.

Quest Diagnostics Incorporated

33608 Ortega Highway
San Juan Capistrano, CA 92675-2042
949.728.4000
www.QuestDiagnostics.com

Quest Diagnostics

There is no evidence that this couple was told of these chances for misdiagnosis. These embryos should only have been transferred with documentation that the parents were informed about the significant risks of having an affected embryo transferred.

There is a long discussion in the deposition of Mark Hughes as to the requirements for every couple undergoing PGD to have an invasive prenatal diagnostic procedure. In fact, Mark Hughes mentioned that he would have refused to do the case if he had known the couple would not have had a prenatal diagnosis. He states that the reason for this is for quality assurance purposes only and not for the purposes of pregnancy termination. This is belied by the facts. Quality Assurance can be obtained by testing umbilical chord blood at the time of delivery if a couple has eschewed a prenatal diagnosis. In fact no effort was made to determine the results of any prenatal diagnosis since Mark Hughes, by his own admission, was not aware that the couple had not had a prenatal diagnosis. The lab also obviously made no effort to obtain umbilical chord blood or a peripheral blood sample.

The notification that the Grossbaum's baby was affected with CF came not at the instigation of the laboratory but from a phone call from some unidentified person in New York. In fact the lab actually believed twins were born when it was a singleton birth. The failure to follow-up on the results of PGD shows a stunning lack of Quality Assurance in the laboratory. If the only reason they were aware an affected child was born was an anonymous phone call, how many other misdiagnoses have occurred that they are not aware of?

Most couples requesting PGD do so because they are opposed to option of prenatal diagnosis with subsequent termination of affected fetuses. The reasons behind this may by religious belief, ethical stance, or emotional trauma due to previous instances of terminating affected fetuses. If a couple such as the Grossbaum's were in religious opposition to abortion, the only reason for them to have an invasive prenatal diagnostic procedure would be either reassurance (if the prenatal diagnosis showed an unaffected child) or preparedness (should the prenatal diagnosis reveal an affected child). Invasive prenatal diagnosis either by CVS or amniocentesis carries risks of miscarriage so the choice of refusing a prenatal diagnostic procedure was a reasonable and understandable decision by this couple. Since they would not have terminated an affected fetus anyway, even if they had elected to have a prenatal diagnosis would not have prevented the birth of an affected child because of their religious prohibition of abortion.

Quest Diagnostics Incorporated

33608 Ortega Highway
San Juan Capistrano, CA 92675-2042
949.728.4000
www.QuestDiagnostics.com

Quest
Diagnostics

In 2004, the state of PGD was in such an advanced state that with competent laboratory practice (using linked markers with or without polar body), coercing someone into having a prenatal diagnostic procedure against their will in order to qualify for PGD is distasteful at best and abusive at worst.

I am also concerned about the informed consent process. I see a form entitled "Pre-Case Phone Review of PDG Informed Consent" dated 03/25/2004. This seems to be notes from a telephone conversation between Mark Hughes and the Grossbaum's. However the signed informed consent is dated 6/4/2004, 71 days later. The informed consent is witnessed, signed and dated 6/4/2004 by the Grossbaum's and a witness with an unrecognizable signature. The signature line for the principal investigator is signed Mark Hughes but dated 7/16/04, 35 days later. The pertinent question is who actually obtained the informed consent and was this individual competent to answer all questions and re-explain all procedures since PGD is complex and 71 days had passed between the initial telephone counseling session and the signing of the informed consent.

I am reproducing 2 paragraphs from the federal register pertinent to this point. These are direct quotes from ***21 CFR 50.25 Elements of informed consent.*** This document is available at: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm116333.htm

"The clinical investigator is responsible for ensuring that informed consent is obtained from each research subject before that subject participates in the research study. FDA does not require the investigator to personally conduct the consent interview. The investigator remains ultimately responsible, even when delegating the task of obtaining informed consent to another individual knowledgeable about the research....
The IRB should be aware of who will conduct the consent interview. The IRB should also be informed of such matters as the timing of obtaining informed consent and of any waiting period (between informing the subject and obtaining the consent) that will be observed."

These regulations require notification to the Institutional Review Board (IRB) if there is a waiting period between informing the subject and obtaining the consent. Was the notification made? Alternatively if the entire consent process was recreated on 6/4/2004 who administered the informed consent, how knowledgeable is that individual with respect to PGD, and was the IRB notified that this individual was conducting the informed consent process.

Quest Diagnostics Incorporated

33608 Ortega Highway
San Juan Capistrano, CA 92675-2042
949.728.4000
www.QuestDiagnostics.com

Quest
Diagnostics

In my opinion the care given to the Grossbaum's was clearly well below acceptable standards. The couple was not given the opportunity to select a more accurate procedure than the one they were offered. There was no discussion of the risks of using blastomere biopsy without linked markers in a compound heterozygous situation. The fault was clearly on the part of Mark Hughes since he provided the expert consultation and administered the informed consent to the patient. Whether or not NYU has culpability because they trusted that their patients were receiving adequate care from Genesis Genetics, the self proclaimed inventors of PGD, is open for discussion.

Respectfully submitted.

Charles M. Strom, M.D., Ph.D., F.A.A.P., F.A.C.M.G., H.C.L.D.
Medical Director, Genetic Testing Center
Quest Diagnostics Nichols Institute